



[EPA-HQ-OPPT-2023-0627; FRL-11598-01-OCSPP]

TSCA New Chemicals Program Decision Framework for Hazard Identification of Eye Irritation and Corrosion; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of a new document supporting the new chemicals program under the Toxic Substances Control Act (TSCA) titled “New Chemicals Program Decision Framework for Hazard Identification of Eye Irritation and Corrosion.” The document provides a decision framework for use by the Office of Pollution Prevention and Toxics (OPPT) New Chemicals Division (NCD) for identification of eye irritation or corrosion hazards for new chemical substances based on prioritization of reproducible, human-relevant data. The Framework supports EPA’s mandate under TSCA to promote the development and implementation of alternative test methods and strategies, or New Approach Methodologies (NAMs), to reduce, refine or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0627, is available online at <http://www.regulations.gov>. Additional instructions for visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Renee Beardslee, New Chemical Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8787; email address: beardslee.renee@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South

Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action is directed to the public in general. This notice may be of specific interest to persons who are or may be interested in risk assessments of new chemical substances under TSCA (e.g., submitters of TSCA 5 notices, industry, non-governmental organizations (NGOs), and academia). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

II. What action is the Agency taking?

EPA is announcing the availability of a new decision framework for use by the New Chemicals Division (NCD) of the Office of Pollution Prevention and Toxics (OPPT) for identification of eye irritation or corrosion hazards for new chemical substances based on prioritization of reproducible, human-relevant data. The document supports EPA's efforts to develop NAMs that do not require vertebrate animal testing and furthers the agency's commitment to reduce and replace the use of vertebrate animals in the testing of chemical substances and mixtures.

TSCA section 4(h)(2)(A) directs EPA to "promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment."

To incorporate alternative test methods and strategies, or NAMs, data for eye irritation and corrosion hazard identification into the new chemicals program risk assessment process, NCD developed a framework for new chemical risk assessments that prioritizes reproducible, human-relevant in vitro data. The Framework is based upon existing peer-reviewed literature, accepted Organization for Economic Cooperation and Development (OECD) test guidelines, and

other existing accepted risk assessment approaches.

NCD is responsible for conducting risk assessments for new chemical substances submitted under TSCA section 5 authority. NCD expects multiple benefits from the incorporation of this proposed Framework in its assessment including: 1) progress towards fulfilling TSCA section 4(h)(2) statutory requirements; 2) transparency for stakeholders regarding EPA's process of hazard identification of eye irritation and corrosion for new chemical submissions; 3) clear scientific rationale for identification of eye irritation and corrosion hazards for human health assessors leading to improved consistency across final new chemical risk assessments; and 4) use of the most reproducible, human-relevant scientific data for decision-making.

III. Does this Framework Impose Binding Requirements?

This document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the Framework, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the Framework document and any statute, regulation, or other legally binding document, the Framework document will not be controlling.

IV. Is this Framework subject to the Paperwork Reduction Act (PRA)?

This action does not contain any new or revised information collections or burden subject to additional OMB approval under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). Information collection activities contained in the TSCA new chemicals program are already approved by OMB under the PRA and are assigned OMB Control No. 2070-0038 (EPA ICR No. 1188.14).

Authority: 15 U.S.C. 2604 *et seq.*

Dated: January 3, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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